

PATENT  
670001-2002.5  
USSN 09/805,427

### AMENDMENT

Kindly amend the application, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, as follows:

#### IN THE SPECIFICATION

Please amend the application at page 1, first full paragraph (under the "Related applications" section) to read as follows:

C  
B<sup>1</sup>  
--This application is a continuation-in-part of US 09/246,191, filed December 30, 1998, which claims priority from US provisional application 60/070,488, filed 5 January 1998. Reference is also made to: the concurrently-filed US application of Andersen et al., Serial No. 09/804,980; US application Serial No. 09/289,388 filed 12 April 1999, which is a continuation of US application Serial No. 08/465,640 filed 5 June 1995, now US Patent No. 5,955,077, issued September 21, 1999, which is a continuation-in-part of US 08/123,182 filed 20 September 1993, now abandoned, and a continuation-in-part of PCT/DK94/00273, filed July 1, 1994, published as WO95/01441, and claiming priority from Danish application 0798/93, filed July 2, 1993; US application Serial No. 09/050,739 filed 30 March 1998, which is claims priority from US provisional application Serial No. 60/044,624 filed 18 April 1997; Andersen et al., application Serial No. 09/791,171, filed 20 February 2001, as a divisional of U.S. application Serial No. 09/050,739; and commonly-owned U.S. Patent No. 6,120,776--

#### IN THE CLAIMS

Kindly add new claims 26-30, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents as follows:

C<sup>8</sup>  
B<sup>2</sup>  
--26. (New) A pharmaceutical composition which comprises an immunologically responsive amount of at least one member selected from the group consisting of:

- (a) a fusion polypeptide which comprises a first amino acid sequence including at least one stretch of amino acids constituting a T-cell epitope derived from the M. tuberculosis protein ESAT-6, and a second amino acid sequence including at least one stretch of amino acids constituting a T-cell epitope derived from the M. tuberculosis protein AG85B, said first and second amino acid sequences optionally being fused via a linker sequence;

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- sb  
c8
- (b) a polypeptide comprising an amino acid sequence which has a sequence identity of at least 70% to any one of said polypeptides in (a) and at the same time being immunogenic; and
  - (c) a fusion polypeptide comprising at least one polypeptide or amino acid sequence according to (a) or (b) and at least one fusion partner.

27. (New) Immunogenic composition according to claim 10 or pharmaceutical composition according to claim 26, characterized in that said immunogenic composition/pharmaceutical composition can be used prophylactically in a subject not infected with a virulent mycobacterium; or therapeutically in a subject already infected with a virulent mycobacterium.

- 28 (New) A method for producing a polypeptide according to claim 1, comprising
- (a) inserting a nucleic acid fragment which comprises a nucleic acid sequence which encodes the polypeptide, or which comprises a nucleic acid sequence complementary thereto into a vector which is able to replicate in a host cell, introducing the resulting recombinant vector into the host cell, culturing the host cell in a culture medium under conditions sufficient to effect expression of the polypeptide, and recovering the polypeptide from the host cell or culture medium; or
  - (b) isolating Ag85B and ESAT-6 from a whole mycobacterium, from culture filtrate or from lysates or fractions thereof, and fusing the polypeptides;
  - (c) synthesizing the polypeptide e.g. by solid or liquid phase peptide synthesis; or
  - (d) a combination of the methods in (a), (b) and/or (c).

29. (New) The method of claim 28 wherein the mycobacterium is *Mycobacterium tuberculosis*, *Mycobacterium africanum* or *Mycobacterium bovis*.

30. (New) The polypeptide according to claim 1 which contains a T-cell epitope of ESAT-6 and a T-cell epitope of Ag85B.

31. (New) A method for stimulating an immune response comprising administering to an animal the polypeptide of claim 1, or the immunogenic composition of claim 10 or the pharmaceutical composition of claim 26, in an amount sufficient to elicit the immune response.

#### IN THE INVENTIVE ENTITY

Kindly amend the inventive entity, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents as follows:

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If the restriction requirement is maintained, then please delete Rikke Skjot as a named inventor as it is verily believed that this individual is not a named inventor of the subject matter of the claims that will be under examination if the restriction requirement is maintained and the election of Group I is accepted and only the subject matter of Group I is in the claims being examined.